DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 3, 2015

Datex-Ohmeda, Inc.
Ms. Trishia Dwyer
Regulatory Affairs Leader
Post Office Box 7550
Madison, WI 53707

Re: K140575
Trade/Device Name: GE Datex-Ohmeda Engström Carestation and Engström Pro
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: December 29, 2014
Received: December 31, 2014

Dear Ms. Dwyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140575

Device Name: GE Datex-Ohmeda Engström Carestation and Engström Pro

Indications For Use:

The GE Datex-Ohmeda Engström Carestation and Engström Pro are designed to provide mechanical ventilation for adults and pediatrics weighing 5kg and above having degrees of pulmonary impairment varying from minor to severe. Optional Neonatal capabilities on Engström Carestation and Engström Pro expand the patient range to 0.25 kg.

The GE Datex-Ohmeda Engström Carestation and Engström Pro are microprocessor based, electronically controlled, pneumatically driven ventilators that include integrated FiO2, airway pressure, spirometry, and volume monitoring. Options include an Aerogen Aeroneb nebulizer, data capture accessory and an integrated air compressor. Options available on Engström Carestation only include integrated respiratory gas monitoring capabilities via various Datex-Ohmeda patient monitoring modules listed in the product labeling, capabilities to measure SpiroDynamics via an intratracheal pressure sensor in patients using sized 6.5 tracheal tubes and larger, and calculation of functional residual capacity of mechanically ventilated patients using Nitrogen Wash In/Wash Out method.

Not all features are available with all patient populations.

The Engström Carestation is not a pulmonary function calculation device.

The system is designed for facility use, including within-facility transport, and should only be used under the orders of a clinician.

Prescription Use _XXX_	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

GE Healthcare

Datex-Ohmeda Inc.
3030 Ohmeda Drive
P.O. Box 7550
Madison, WI 53707-7550 USA

Premarket Notification 510(k) Summary
As required by section 807.92
Engström Carestation and Engström Pro

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda, Inc.
3030 Ohmeda Drive
PO Box 7550
Madison, WI 53707-7550 USA
Tel: 608-221-1551 x 500-3260
Fax: 608-646-6488

NAME OF CONTACT:

Ms. Trishia Dwyer
Ms. Monica Morrison (alternate)

DATE:

March 5, 2014

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Engström Carestation
Engström Pro

COMMON NAME:

Ventilator, Continuous

CLASSIFICATION NAME:

ventilator, continuous, facility use

CDRH PRODUCT CODE:

CBK

REGULATION NUMBER:

CBK: 21 CFR 868.5895

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Engström Ventilator is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Engström Ventilator (K111116).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The GE Datex-Ohmeda Engström Carestation and Engström Pro are flexible, adaptable, and intuitive, critical care ventilators. A wide selection of performance options gives the user full control of the system configuration. The Engström Carestation and Engström Pro feature patient monitoring, patient ventilation, and the capability of interfacing with central information management systems.

Both the GE Datex-Ohmeda Engström Carestation and Engström Pro are designed to provide mechanical ventilation for adults and pediatrics weighing 5kg and above having degrees of pulmonary impairment varying from minor to severe. Optional Neonatal capabilities allow the Engström Carestation and Engström Pro to be used with patients weighing 0.25 kg and above.

The modes of ventilation currently available include:

1. Volume Controlled (VCV)
2. Pressure Controlled (PCV)
3. Pressure Controlled, Volume Guaranteed (PCV-VG)
4. Synchronized Intermittent Mandatory Ventilation, Volume Controlled (SIMV-VC)
5. Synchronized Intermittent Mandatory Ventilation, Pressure Controlled (SIMV-PC)
6. Synchronized Intermittent Mandatory Ventilation, Pressure Controlled Volume Guarantee (SIMV-PCVG)
7. Bi-level Airway Pressure Ventilation
8. Constant Positive Airway Pressure/Pressure Support Ventilation (CPAP/PSV)
9. Apnea backup (available in SIMV-VC, SIMV-PC, SIMV-PCVG/BiLevel-VG, BiLevel, CPAP/PSV, and VG-PS)
10. Non-invasive ventilation (NIV), not available in neonatal mode
11. Infant Nasal CPAP (nCPAP), only available in neonatal mode
12. Volume Guarantee, Pressure Support (VG-PS), only available in neonatal mode

The GE Datex-Ohmeda Engström Carestation and Engström Pro are microprocessor based, electronically controlled, pneumatically driven ventilators that include integrated FiO2, airway pressure, spirometry and volume monitoring and an Aerogen Aeroneb Pro nebulizer control board.

The ventilator consists of two main components: a display and a ventilator unit. The display allows the user to interface with the system and control settings through use of soft keys on the display, a com wheel, and a resistive touch screen. The Engström Carestation also includes a module bay that allows the integration of various Datex-Ohmeda patient monitoring modules with the ventilator.

The user interface for control of nebulization is provided via the ventilator display unit. The standard nebulizer board is provided with both the Engström Carestation and Engström Pro variants. Users have the option to configure the system to use an external pneumatic nebulizer in place of the standard nebulizer.

The optional medical air compressor is intended for use as an accessory to provide a dry, filtered, breathable compressed air supply. The compressor is installed in the base of the ventilator cart. The

compressor is powered from AC mains only. A source of compressed oxygen is required to be connected to Engström Carestation/Engström Pro equipped with the optional compressor. The use of an integrated air compressor was first cleared in K050597.

Optional accessories common to both Engström Carestation and Engström Pro include a trolley/cart, integrated air compressor, support arm, humidifier and water trap mounting brackets, and a data capture accessory. Additional optional accessories specific to the Engström Carestation include airway modules, intratracheal pressure sensor, auxiliary electrical outlets, and module bay. Optional functionality specific to the Engström Carestation includes integrated respiratory gas monitoring, capabilities to measure SpiroDynamics via a GE supplied intratracheal pressure sensor in patients using sized 6.5 tracheal tubes and larger, and calculation of functional residual capacity of mechanically ventilated patients using Nitrogen Wash In/Wash Out method. The integrated respiratory gas monitoring is provided via the Datex-Ohmeda Gas Modules, M-C, M-CO, M-COV, M-COVX, M-CaiO, M-CAiOV, M-CAiOVX, rev 3.2 software and higher (K001814), E-CO, E-COV, E-COVX, E-CAiO, E-CAiOV, E-CAiOVX (K051092), or M-Mini-CO2 Module (K023454) or E-MiniC module (K052582) which are physically integrated into the Engström Carestation, receive electronic power from the Engström Carestation and communicate measured values to the Engström Carestation for display on the system display unit.

INTENDED USE as required by 807.92(a)(5)

The GE Datex-Ohmeda Engström Carestation and Engström Pro are designed to provide mechanical ventilation for adults and pediatrics weighing 5kg and above having degrees of pulmonary impairment varying from minor to severe. Optional Neonatal capabilities on Engström Carestation and Engström Pro expand the patient range to 0.25 kg.

The GE Datex-Ohmeda Engström Carestation and Engström Pro are microprocessor based, electronically controlled, pneumatically driven ventilators that include integrated FiO2, airway pressure, spirometry, and volume monitoring. Options include an Aerogen Aeroneb nebulizer, data capture accessory, and an integrated air compressor. Options available on Engström Carestation only include integrated respiratory gas monitoring capabilities via various Datex-Ohmeda patient monitoring modules listed in the product labeling, capabilities to measure SpiroDynamics via an intratracheal pressure sensor in patients using sized 6.5 tracheal tubes and larger, and calculation of functional residual capacity of mechanically ventilated patients using Nitrogen Wash In/Wash Out method.

Not all features are available with all patient populations.

The Engström Carestation is not a pulmonary function calculation device.

The system is designed for facility use, including within-facility transport, and should only be used under the orders of a clinician.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The GE Datex-Ohmeda Engström ventilator has been updated from the predicate version (K111116). There have been no changes to the intended use or fundamental scientific technology.

This 510(k) requests clearance to add an alternate integrated air compressor to the Engstrom Carestation and Engstrom Pro accessory list. The alternate air compressor, the EVair differs from the predicate (cleared under K050597) in that it contains improvements in acoustics, vibration, and thermal dissipation.

The EVair compressor was designed specifically for the Engström family of products (Engström Carestation and Engström Pro). It fits in the back of the Engström cart and acts as a source of compressed air. The EVair is not available as a stand-alone compressor; it is only available as an accessory to the Engström Carestation and Pro. The new integrated compressor, EVair is manufactured by IMTMedical. The addition of the alternate compressor, EVair, does not affect the safe or effective use of the ventilator as the compressor interfaces with the ventilator in the same manner, and performs in an equivalent manner. There is no change to the Engstrom performance as a result of this change. Additionally, the EVair compressor performs in a functionally equivalent manner to the predicate, EVair03.

Please see the table below for a comparison of the predicate Engstrom Carestation and Engstrom Pro (K111116) compared to the modifications proposed in this 510(k):

	Engstrom Carestation, Engstrom Pro 7.x software (K111116)	**Engstrom Carestation and Engstrom Pro (this 510(k))**	**Comments/Equivalence**
Indications for Use	The GE Datex-Ohmeda Engström family of ventilators (Engström Carestation and Engström Pro) are designed to provide mechanical ventilation for adults and pediatrics weighing 5kg and above having degrees of pulmonary impairment varying from minor to severe. Optional Neonatal capabilities on Engström family expand the patient range to 0.25 kg. The GE Datex-Ohmeda Engström family of ventilators are microprocessor based, electronically controlled, pneumatically driven ventilators that include integrated FiO2, airway pressure, spirometry and volume monitoring. Options include an Aerogen Aeroneb nebulizer, data capture accessory and an integrated air compressor. Options available on Engström Carestation only	The GE Datex-Ohmeda Engström Carestation and Engström Pro are designed to provide mechanical ventilation for adults and pediatrics weighing 5kg and above having degrees of pulmonary impairment varying from minor to severe. Optional Neonatal capabilities on Engström Carestation and Engström Pro expand the patient range to 0.25 kg. The GE Datex-Ohmeda Engström Carestation and Engström Pro are microprocessor based, electronically controlled, pneumatically driven ventilators that include integrated FiO2, airway pressure, spirometry, and volume monitoring. Options include an Aerogen Aeroneb nebulizer, data capture accessory, and an integrated air compressor. Options	Identical to Engstrom 7.X (K111116) Indications for Use. Only change is to reference to product name, Engstrom Carestation and Engstrom Pro instead of Engstrom family of ventilators.

	Engstrom Carestation, Engstrom Pro 7.x software (K111116)	Engstrom Carestation and Engstrom Pro (this 510(k))	Comments/Equivalence
	include integrated respiratory gas monitoring capabilities via various Datex-Ohmeda patient monitoring modules listed in the product labeling, capabilities to measure SpiroDynamics via an intratracheal pressure sensor in patients using sized 6.5 tracheal tubes and larger, and calculation of functional residual capacity of mechanically ventilated patients using Nitrogen Wash In/Wash Out method. Not all features are available with all patient populations. The Engström Carestation is not a pulmonary function calculation device. The system is designed for facility use, including within-facility transport, and should only be used under the orders of a clinician.	available on Engström Carestation only include integrated respiratory gas monitoring capabilities via various Datex-Ohmeda patient monitoring modules listed in the product labeling, capabilities to measure SpiroDynamics via an intratracheal pressure sensor in patients using sized 6.5 tracheal tubes and larger, and calculation of functional residual capacity of mechanically ventilated patients using Nitrogen Wash In/Wash Out method. Not all features are available with all patient populations. The Engström Carestation is not a pulmonary function calculation device. The system is designed for facility use, including within-facility transport, and should only be used under the orders of a clinician.	
Ventilation Modes	1. Volume Controlled (VCV), 2. Pressure Controlled (PCV), 3. Pressure Controlled, Volume Guaranteed (PCV-VG), 3. Pressure Controlled, Volume Guaranteed (PCV-VG), 4. Synchronized Intermittent Mandatory Ventilation, Volume Controlled (SIMV-VC), 5. Synchronized Intermittent Mandatory Ventilation, Pressure Controlled (SIMV-PC), 6. Synchronized Intermittent Mandatory Ventilation, Pressure Controlled Volume Guarantee (SIMV-PCVG), 7. Bi-level Airway Pressure Ventilation 8. Constant Positive Airway Pressure/ Pressure Support	1. Volume Controlled (VCV), 2. Pressure Controlled (PCV), 3. Pressure Controlled, Volume Guaranteed (PCV-VG), 3. Pressure Controlled, Volume Guaranteed (PCV-VG), 4. Synchronized Intermittent Mandatory Ventilation, Volume Controlled (SIMV-VC), 5. Synchronized Intermittent Mandatory Ventilation, Pressure Controlled (SIMV-PC), 6. Synchronized Intermittent Mandatory Ventilation, Pressure Controlled Volume Guarantee (SIMV-PCVG), 7. Bi-level Airway Pressure Ventilation 8. Constant Positive Airway Pressure/ Pressure Support	Identical to Engstrom 7.X (K111116). No change to the ventilation modes.

	Engstrom Carestation, Engstrom Pro 7.x software (K111116)	**Engstrom Carestation and Engstrom Pro (this 510(k))**	**Comments/Equivalence**
	Ventilation (CPAP/PSV), 9. Apnea backup (available in SIMV-VC, SIMV-PC, SIMV-PCVG/BiLevel-VG, BiLevel, CPAP/PSV, and VG-PS), 10. Non-invasive ventilation (NIV), 11. Nasal CPAP (nCPAP). 12. Volume Guaranteed, Pressure Support (VG-PS) Note: NIV is not available in neonatal mode. VG-PS and nCPAP are only available in neonatal mode.	Ventilation (CPAP/PSV), 9. Apnea backup (available in SIMV-VC, SIMV-PC, SIMV-PCVG/BiLevel-VG, BiLevel, CPAP/PSV, and VG-PS), 10. Non-invasive ventilation (NIV), 11. Nasal CPAP (nCPAP). 12. Volume Guaranteed, Pressure Support (VG-PS) Note: NIV is not available in neonatal mode. VG-PS and nCPAP are only available in neonatal mode.	
Engstrom Ventilator System Software	Version 7.X	Version 7.X	Substantially equivalent. Minor software updates only have been made with no change to the features or function of the ventilator.
Optional Integrated Air Compressor	Integrated Air Compressor option available (called EVair03)	Integrated Air Compressor option available (called EVair)	Functionally equivalent to Engstrom 7.X (K111116). Verification has demonstrated that the EVair compressor is functionally equivalent to the predicate EVair03 compressor.
Air Compressor: Transition to backup air supply for Engstrom	Pneumatic control to switch from standby to reserve air supply. Backup operation begins when pipeline pressure drops below 250 kPa (36.3 psi).	Software control to switch from standby to reserve air supply. Backup operation begins when pipeline pressure drops below 280 kPa (40.6 psi), this is a factory set-point but can be adjusted by trained service personnel.	The backup operation of the EVair is substantially equivalent to the predicate EVair03. Pressure values still fall within the Engstrom ventilator specifications. No functional change to the Engstrom Ventilator, the EVair has been verified to be functionally equivalent to the EVair03 compressor.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The GE Datex-Ohmeda Engstrom Carestation and Engström Pro ventilators with the integrated compressor have been thoroughly tested through verification of specifications and validation, including software validation. Verification of compliance with applicable standards has also been completed to ensure safe use of the device in its intended use environment. The following quality assurance measures were applied during the development of the Engstrom ventilator system:

- Risk Analysis
- Requirements/Specification Reviews
- Design Reviews
- Testing on unit level
- Integration testing
- Performance Testing (Verification)
- Safety Testing (Verification)

SUMMARY OF CLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(2)

The modifications made to the Engström ventilator did not require clinical testing. The compressor improvements as described in this submission were completely evaluated by non-clinical tests to verify and validate the safety and functionality of the ventilator.

CONCLUSION:

The summary above demonstrates that there are no new questions of safety and effectiveness for the Engström Carestation and Engström Pro ventilators as compared to the predicate devices. Based on the performance data, GE Healthcare considers the Engström Carestation and Engström Pro ventilators to be as safe and effective, and perform in a substantially equivalent manner to the predicate devices.